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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/13/2005

Brad St. Croix

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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,805	Applicant(s) ST. CROIX ET AL.	
	Examiner MEERA NATARAJAN	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 26, 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/30/2009 has been entered.
2. Claims 23, 24, 26 and 27 are pending and will be examined on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter et al. (J. of Histochemistry and Cytochemistry, Vol. 43, No.8 pp. 791-800, 1995).
5. The Claims are drawn to method of identifying tumor endothelial cells comprising contacting a population of tumor cells in a tissue sample containing endothelial cells with one or more antibodies which bind specifically to secreted protein, acidic, cysteine-rich (SPARC or osteonectin).

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6. Porter et al. teach sections of human tumors immunostained with anti-SPARC Mab demonstrate SPARC in renal cell carcinoma, adenocarcinoma of lung, adenocarcinoma of breast, giant-cell tumor of bone, astrocytes in a low grade glioma, and endometrial adenocarcinoma (see Figure 5 and 6). Porter et al. disclose low levels of SPARC expression in normal human tissues. In contrast, there were significantly elevated levels of SPARC in malignant tissue. Porter et al. propose that SPARC expression might contribute to some aspects of tumor progression.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 23, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (J. of Histochemistry and Cytochemistry, Vol. 43, No.8

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pp. 791-800, 1995) in view of Long et al. (PgPub 20040214241) and Taniguchi et al. (Int. J. Cancer, Vol. 86, pp.799-805, June 2000).

10. The Claims are drawn to method of identifying tumor endothelial cells comprising contacting a population of tumor cells in a tissue sample containing endothelial cells with one or more antibodies which bind specifically to secreted protein, acidic, cysteine-rich (SPARC or osteonectin) and isolating said tumor endothelial cells.

11. The teachings of Porter et al. are presented in the 102(b) rejection set forth above. Porter et al. does not teach isolating tumor endothelial cells. This deficiency is made up for by Long et al. and Taniguchi et al.

12. Long et al. disclose a method of obtaining a population of cells, from bone marrow, bone (tissue), or peripheral blood cells (bodily fluid), contacting said cells with an antibody, and removing cells of the population that do not immunoreact with said antibody (See sections [0035-0038]). Claims 16 and 18-20 of Long et al. disclose the use of an osteonectin antibody to isolate specific cells.

13. Taniguchi et al. disclose tumor vascular endothelial cells have been identified as a new target for cancer therapy. Tumor vessels are more suitable target than tumor cells for the following reasons: (i) tumor endothelial cells are genetically stable and do not develop acquired drug resistance, (ii) systemically administered drugs have better access to TECs than tumor cells and (iii) damage of TECs and tumor vessels leads to tumor regression.

14. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the antibody disclosed in Porter et al. or

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Long et al. to isolate tumor endothelial cells in tissue or bodily fluid samples as described in Long et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Porter et al., Long et al., and Taniguchi et al., because Taniguchi et al. teach tumor endothelial cells have been identified as a new target for cancer therapy and cultures of tumor endothelial cells need to be cultivated by isolating them from tumor samples to test new anti-cancer therapies.

All previous rejections are withdrawn in view of Applicant's arguments in the reply filed 06/30/2009.

Conclusion

15. Claims 23, 24, 26 and 27 are rejected.
16. No Claim is allowed.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643